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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MATTHEW S. REIMINK
and MATTHEW F. OGLE

Appeal 2009-0400
Application 09/475,721[1]
Technology Center 1700

Decided:[2] March 13, 2009

Before ADRIENE LEPIANE HANLON, JEFFREY T. SMITH, and MARK NAGUMO, *Administrative Patent Judges*.

NAGUMO, *Administrative Patent Judge.*

DECISION ON APPEAL

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[1] Application 09/475,721, *Medical Devices with Polymer/Inorganic Substrate Composites*, filed 30 December 1999. The specification is referred to as the "721 Specification," and is cited as "Spec." The real party in interest is listed as St. Jude Medical, Inc. (Appeal Brief, filed 21 June 2007 ("Br."), 2.)

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the Decided Date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

A. Introduction

Matthew S. Reimink and Matthew F. Ogle ("Reimink") timely appeal under 35 U.S.C. § 134(a) from the final rejection[3] of claims 1-3, 5-20, 31, and 32. We have jurisdiction under 35 U.S.C. § 6(a). We AFFIRM-IN-PART.

The subject matter on appeal relates to flexible biocompatible medical devices that contact a patient's bodily fluids. The devices have an inorganic substrate, which provides mechanical properties such as flexibility, and a polymer that covers the substrate and that provides the ultimate form or geometry for the device as well as the biocompatibility.

Representative Claims 1 and 10 are reproduced from the Claims Appendix to the Principal Brief on Appeal:

Claim 1

A medical device comprising

[**a**] a composite having an inorganic substrate and

[**b**] a polymer applied on all of the substrate surfaces,

[**1**] the polymer forming a structure shaped differently from the structure of the substrate, and

[**2**] providing the form of the device.

(Claims App., Br. 15; bracketed labels and indentation added.)

Claim 10

A medical device comprising a flexible composite component comprising

[**a**] an inorganic substrate and

[**b**] a polymer member covering the substrate, wherein

[3] Office action mailed 14 December 2006.

> [**1**] the flexible composite component can be bent through a cross section of the flexible component composite, and wherein
>
> [**2**] the polymer member contacts bodily fluids and separates the bodily fluids from the substrate.

(Claims App., Br. 16; bracketed letter labels and indentation added.)

The Examiner has maintained the following grounds of rejection:[4]

A. Claims 1-3, 8, and 9 stand rejected under 35 U.S.C. § 102(b) in view of Reul.[5]

B. Claims 5-7, 31, and 32 stand rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Pietsch.[6]

C. Claims 10, 11, and 16-19 stand rejected under 35 U.S.C. § 102(b) in view of Reul.

D. Claims 12-14 stand rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Pietsch.

E. Claim 15 stands rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Lenkei.[7]

F. Claim 20 stands rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Sumitomo.[8]

Reimink limits its substantive arguments for patentability to independent claims 1 (Rejection A) and 10 (Rejection C). Accordingly, as to Rejections A and C, the rejected dependent claims stand or fall with the respective independent claims. 37 C.F.R. § 41.37(c)(1)(vii). As to

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[4] Examiner's Answer mailed 15 October 2008. ("Ans.").

[5] Helmut Reul and Ernst-Wilhelm Müller, *Prosthetic Closure Devices to Replace the Valves in Human Hearts*, U.S. Patent 4,263,680 (1981).

[6] Hans Pietsch et al., U.S. Patent 4,778,461 (1988).

[7] Andrew Lenkei, U.S. Patent 4,597,767 (1986).

[8] Sumitomo Electric Co., Abstract of JP 59-192,366.

Rejections B, D, E, and F, which address claims that dependent from claims 1 and 10, we have considered these grounds of rejection based on the arguments advanced in support of the patentability of the respective independent claims.

Regarding Rejection A of claim 1, Reimink contends that the Examiner erred in finding that Reul describes a device in which the polymer coating forms a structure shaped differently from the structure of the substrate. (Br. 8-9.) According to Reimink, a dipping process, such as that used by Reul, "places a layer having a substantially uniform thickness onto the inorganic substrate that conforms to the general shape of the substrate." (Br. 8.) More particularly, Reimink argues that "[i]nterconnections created by filling in the voids created by the apertures between the outer surfaces of the valve member do not affect the form of the device as claimed. The synthetic material coating still conforms to the shape of the substrate." (*Id.* at 9.) Reimink argues further that the hinge **4** is an internal structure that "cannot provide a form of the device as claimed." (*Id.*)

The Examiner responds that "[t]he shape of a structure with spaces is changed to one without spaces." (Ans. 12, citing the 721 Specification, page 19, lines 27-29, as supporting this claim interpretation and finding.) Moreover, the Examiner maintains that the hinge flap **7** is formed in one piece with the valve member, and that the shape and form of the coated article is therefore different from the shape of the inorganic substrate. (*Id.* at 12-13.)

The dispositive issue regarding the patentability of claim 1 (and therefore Rejections A and B) is whether the Examiner's interpretations of

the limitations "shaped differently" ([**b**][**1**]) and "providing the form" ([**b**][**2**]) are correct.

Regarding Rejection C of claim 10, Reimink contends that the Examiner erred in finding that Reul describes a "heart valve member that can be bent through a cross-section" (Br. 11) merely based on the thickness (0.3-0.4 mm) of the valve member. Such a flexible member, according to Reimink, would make the valve member less responsive in opening and closing, "in direct contrast to the advantages . . . as stated in the Reul Patent." (*Id.*) The Examiner's inherency argument, according to Reimink, is flawed because the Examiner has failed to provide any evidence that the cup-shaped valve described by Reul must flex. (*Id.* at 13.)

The Examiner responds that because the 721 Specification discloses that the flexible device may be made from an inorganic substrate that is a thin metal foil coated with a flexible blood compatible synthetic material, "as interpreted in terms of Appellant's disclosure, the thin composite of Reul . . . will flex, and hence can be bent through a cross-section. Furthermore, it is noted that anything is capable of being bent when enough force is applied." (Ans. 16.)

The dispositive issue regarding the patentability of claim 10 (and therefore Rejections C through F) is whether the cup-shaped valve described by Reul is accurately characterized as a "flexible composite component."

B. Findings of Fact

Findings of fact throughout this Opinion are supported by a preponderance of the evidence of record.

The 721 Specification

1. According to the 721 Specification, the invention relates to a device, suitable for contacting a patient's bodily fluids, comprising "a substrate with a polymer material covering at least a portion of the substrate." (Spec. 1, ll. 4-7.)

2. Several different "aspects" of the invention are described.

3. In a first aspect, "[t]he polymer forms a structure substantially different from the structure of the substrate." (Spec. 3, ll. 8-9.)

4. In a further aspect, "[t]he polymer is applied over the substrate such that the polymer does not conform to the shape of the substrate." (Spec. 3, ll. 20-22.)

5. According to the 721 Specification, "[t]he polymer member can be formed with a relatively complex geometry that is not reflected in the structure of the substrate." (Spec. 6, ll. 27-29.)

6. The 721 Specification teaches further that:

> [a] variety of structural features for the medical article can be introduced into the polymer with or without a structural basis from the inorganic substrate. . . . Suitable polymer structure for addition to the composite that does not result from the substrate include, for example, barbs, anchors, slots and/or holes for sutures and fasteners, such as pins and buttons, for attachment to a secondary assembly.

(Spec. 19, l. 24, through 20, l. 4; see also the amendment to this paragraph filed 10 April 2002, entered in the Request for Continued Examination filed 13 May 2002.)

7. In another aspect, the 721 Specification teaches that "[t]he flexible composite component can be bent, at least, about 10 degrees without extending the material beyond its elastic limit." (Spec. 3, ll. 14-16.)

8. The 721 Specification teaches further that "at the specified level of bending, the composite is not extended beyond its elastic limit, at which point the material would not flex back to approximately its original position." (Spec. 19, ll. 12-15.)

9. In this regard, the 721 Specification states that "flexible components for medical devices generally are expected to flex many millions of time over the lifetime of the medical device." (Spec. 19, ll. 20-22.)

Reul

10. Reul describes a prosthetic closure device to replace certain valves in the human heart. (Reul col. 2, ll. 21-23.)

11. The valve member **1** is said to have a dish-shaped structure that is a segment of a sphere. (Reul col. 2, ll. 32-34.)

12. The spherical segment structure is said to increase the strength of the valve member sufficiently to resist pressure differences of up to 300 mm Hg. (Reul col. 2, ll. 34-38.)

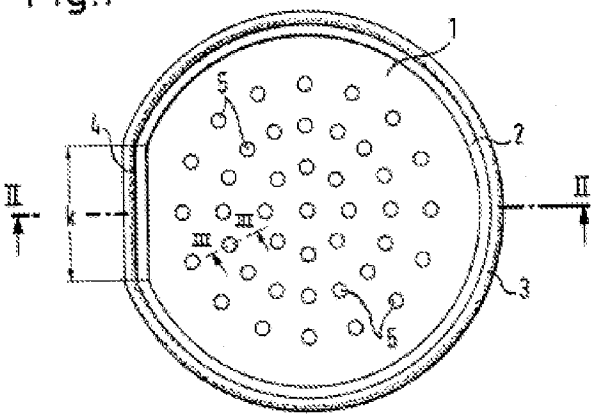
13. Moreover, when used as a mitral valve, the diameter of the spherical segment is selected to be approximately the diameter of the vortex produced behind the dish before the start of ventrical contraction, which vortex is said to cause the valve to close. (Reul col. 2, ll. 51-63.)

14. In preferred embodiments, the thickness of the valve member is said to be less than 0.3-0.4 mm, in order to achieve "very short opening and

closing times," which "guarantees that the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber . . . ". (Reul col. 3, ll. 41-50.)

15. As shown in Reul Figures 1 and 3, which are reproduced *infra*,

Fig.1



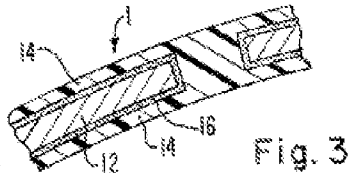


Fig. 3

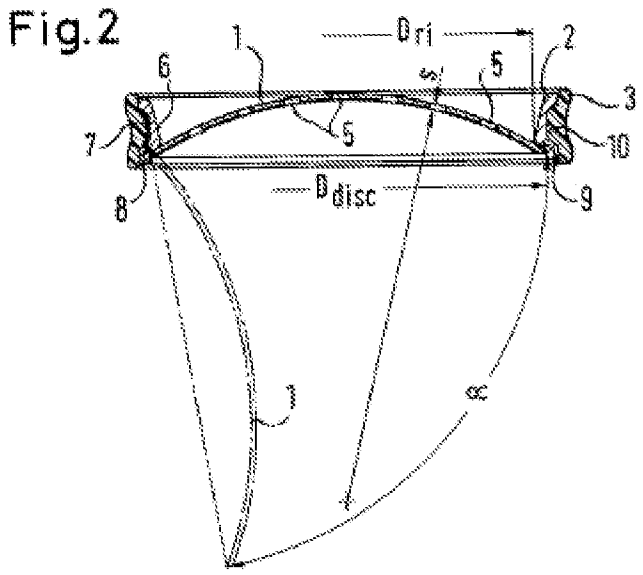
{Figures 1 and 3 are said to show the closure device}[9]

the valve member **1** is described as comprising a metallic material **12**, which is coated on both sides by a blood-compatible synthetic material **14**. (Reul col. 5, ll. 41-43.)

16. The metal substrate **12** is provided with a number of apertures **5** that are completely filled with synthetic material **14** and which permit the synthetic material on each side of the metal to be interconnected, as shown in Figure 3. (Reul col. 5, ll. 45-53.)

[9] The text in curly braces following the Figures is provided to ensure compliance with section 508 of the U.S. Rehabilitation Act for publication of this Decision on the USPTO website pursuant to the Freedom of Information Act. It is not part of the Decision.

17. As shown in Reul Figure 2, which is reproduced *infra*,



{Figure 2 is said to show the valve member **1** in the closed and open (dashed) positions relative to valve body **2**}

the valve member **1** is attached to valve body **2** via a flap **7** (Reul col. 5, ll. 24-27), which is integral with and made of the same synthetic material **14** that covers the substrate **12** (*id.* at col. 4, ll. 39-46).

18. Flap **7** is drawn through slot **8** and fastened in recess **10** to the valve body **2**. (Reul col. 5, ll. 27-35.)

19. In the open position, valve member **1** swings through angle α.

C. Discussion

As the Appellant, Reimink bears the procedural burden of showing harmful error in the Examiner's rejections. *See, e.g., In re Kahn*, 441 F.3d 977, 985-86 (Fed. Cir. 2006) ("On appeal to the Board, an applicant can overcome a rejection [under § 103] by showing insufficient evidence of *prima facie* obviousness") (citation and internal quote omitted).

As our reviewing court has emphasized repeatedly, "the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Reimink does not support its argument that claim 1 limitations [**b**][**1**] and [**2**] do not read on valve member **1** of Reul with definitions from the 721 Specification of the terms "shaped differently" and "form of the device." Thus, Reimink supports its arguments only with general notions of what amounts to a different shape or form. However, the 721 Specification includes, as an aspect of the invention, cases in which "[t]he polymer is applied over the substrate such that the polymer does not conform to the shape of the substrate." (Spec. 3, ll. 20-22.) This aspect aptly describes the coating of Reul substrate **12** by synthetic material **14** in which apertures **5** are filled—i.e., synthetic material **14** does not conform to the shape of the substrate **12** by leaving holes at the positions of apertures **5**. Moreover, as the Examiner points out (Ans. 12), the 721 Specification, at pages 19-20, teaches that polymer structures that do not result from the substrate include structures that assist attachment to a secondary assembly. Reimink has not directed our attention to any disclosures in the 721 Specification that define the terms "shape" or "form" in ways that exclude flap **7** from contributing to the shape or form of the claimed device. We conclude, on the present record, that the flap **7** is indistinguishable from structures that do not result from the substrate.

Reimink has failed to prove harmful error in the rejection of claim 1 and the claims that depend from claim 1. As noted supra, Reimink has not advanced separate arguments for the patentability of claims dependent on claim 1. Accordingly, we AFFIRM Rejections A and B.

Claim 10 stands differently because it requires that the flexible composite component be flexible. It is not enough, as the Examiner argued (Ans. 16), that anything can be bent "when enough force is applied." Rather, as Reimink argues, and as the 721 Specification makes clear, and as the ordinary meaning of the term "flexible" indicates, the flexible composite component must return to its original shape after bending. The Examiner has not directed our attention to any disclosure in Reul that indicates that the spherical segment valve member **1** is "flexible" as required by claim 10—i.e., that it can be "bent through a cross section of the flexible component composite." Rather, review of Reul indicates that the valve member **1** is intended to be rigid so it will react—open and close—almost instantaneously in response to quickly changing pressure gradients. Significant flexibility of valve 1 would appear to be contrary to the valve member properties sought by Reul. While we commend the Examiner's attention to the similar details of the structure of the Reul valve member **1** and the thin coated foils described by Reimink, we caution that the disclosures of references and specifications must be considered as a whole. Not all similar structures will necessarily have the functions and properties sought by a given applicant or patentee.

We conclude that Reimink has shown that the Examiner's misinterpretation of the flexibility limitation [**b1**] in claim 10 is reversible error. Accordingly, we REVERSE Rejection C.

The Examiner relies on additional references in Rejections D, E, and F, as evidence of the obviousness of claims dependent on claim 10 that recite further limitations. As the additional references do not cure the defects of the rejection over Reul, we also REVERSE Rejections D, E, and F.

D. Order

We AFFIRM the rejection of claims 1-3, 8, and 9 under 35 U.S.C. § 102(b) in view of Reul.

We AFFIRM the rejection of claims 5-7, 31, and 32 under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Pietsch.

We REVERSE the rejection of claims 10, 11, and 16-19 under 35 U.S.C. § 102(b) in view of Reul.

We REVERSE the rejection of claims 12-14 under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Pietsch.

We REVERSE the rejection of claim 15 under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Lenkei.

We REVERSE the rejection of claim 20 under 35 U.S.C. § 103(a) in view of the combined teachings of Reul and Sumitomo.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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